Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in March 2002.

New Approvals

ANADA Number: 200-270

Pioneer Product:	138-412
Trade Name:	Iverhart™ Tablets
Ingredients:	Ivermectin
Sponsor:	Blue Ridge Pharmaceuticals, Inc.
Approval Date:	November 30, 2001
Status:	Prescription only
Route:	Oral
Species:	Canine
Drug Form:	Tablet
Concentration:	68, 136, and 272 micrograms per tablet
Indications:	For prevention of heartworm disease by eliminating the tissue stage of heartworm (*Dirofilaria immitis*) larvae for a month after infection.

21CFR 520.1193

Supplemental Approvals

ANADA Number: 200-124

This supplemental application provides for use of flunixin meglumine solution by intravenous injection for control of fever and inflammation in beef cattle and nonlactating dairy cattle (new species).

Trade Name:	Flunixin Meglumine Injection
Ingredients:	Flunixin Meglumine
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	November 1, 2001
Status:	Prescription only
Route:	Intravenous, intramuscular (horses only)
Species:	Horses, cattle (new)
Drug Form:	Liquid (solution)
Concentration:	50 milligrams per millilitter
Indications:	For use in cattle for the following: control of pyrexia associated with bovine respiratory disease and endotoxemia, and control of inflammation in endotoxemia.
Tolerance:	21 CFR 556.286 Flunixin meglumine: Tolerances are established for residues of parent flunixin free acid of 0.125 part per million (ppm) in cattle liver (target tissue) and 0.025 ppm in cattle muscle.
Withdrawal:	4 days

21CFR 522.970

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-123

This supplemental application provides for a new route of administration (subcutaneous) of oxytetracycline injectable solution in cattle.

Trade Name:	Maxim-200®
Ingredients:	Oxytetracycline
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	December 28, 2001
Status:	Over-the-counter
Route:	Intramuscular in swine; intramuscular, intravenous, or subcutaneous in cattle
Species:	Cattle (beef, nonlactating dairy, preruminating veal calves) and swine
Drug Form:	Liquid (solution)
Concentration:	200 milligrams per milliliter
Indications:	**Cattle**: For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. **Swine**: For the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, it is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*
Tolerance:	21CFR 556.500 Oxytetracycline: Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, of 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal:	28 days

21CFR 522.1660

Change of Sponsor Name and Address

From:	G.D. Searle & Co. P.O. Box 5110 Chicago, IL 60680
To:	G.D. Searle LLC, Pharmacia Corp. 4901 Searle Pkwy. Skokie, IL 60077 Labeler Code: 000014

Suitability Petition Action

Number:	02P-0084/CP1
Sponsor:	Pharmaceutical Solutions, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug trimethoprim and sulfadiazine which differs from the pioneer product, Tribrissen® 400 Oral Paste, Schering-Plough Animal Health Corp., NADA 131-918, by the following characteristics: The generic product will consist of a different dosage form (solution), different method of administration (via stomach tube), and different strength from the pioneer.
Action:	Filed on February 26, 2002.